The Critical Need for New Antibiotics

In the U.S., there are not enough antibiotics in development to meet current and anticipated patient needs.

There are only 40 antibiotics in clinical development.*

Historical data show that, generally, only 1 in 5 infectious disease drugs that enter phase 1 trials will receive FDA approval.¹

Products can fail to receive approval for many reasons, including lack of effectiveness or safety concerns.

Antibiotics in Clinical Development With the Potential to Treat Infections Caused by Resistant Gram-Negative ESKAPE Pathogens†

There is a critical need for new therapies to treat deadly infections caused by Gram-negative ESKAPE pathogens—bacteria that are often resistant to available antibiotics. Only a handful of new treatments with the potential to address these serious threats are currently in development.³

† One drug that has completed phase 3 and submitted its New Drug Application to FDA can possibly treat Gram-negative ESKAPE pathogens.

* Total number of antibiotics in phases 1–3 does not add up to 40 because two drugs have completed phase 3 and their New Drug Applications are currently under consideration by FDA.
Urgent threat pathogens

The Centers for Disease Control and Prevention considers three bacteria to be urgent threats to public health. While a number of promising antibiotics with the potential to treat infections caused by these bacteria are in the pipeline, more drug candidates are needed to meet current and future patient needs.

Endnotes


2 The ESKAPE pathogens—Enterococcus faecium, Staphylococcus aureus, Klebsiella pneumoniae, Acinetobacter baumannii, Pseudomonas aeruginosa, and Enterobacter species—cause many infections in the United States and show resistance to many currently available antibiotics. Within the ESKAPE pathogens are key Gram-negative bacteria, including K. pneumoniae, A. baumannii, P. aeruginosa, and Enterobacter species. These pathogens are particularly concerning due to the difficulty in discovering new therapies that can overcome current resistance. Stakeholders often highlight the Gram-negative ESKAPE pathogens as an area in which drug innovation is urgently needed.

3 An antibiotic is considered to have potential to treat resistant Gram-negative ESKAPE pathogens if the drug has in vitro data showing both activity against one or more Gram-negative species that are considered ESKAPE pathogens and the potential for clinically significant improved coverage of resistant isolates of these species relative to currently available antibiotics. For additional information, please see http://www.pewtrusts.org/en/multimedia/data-visualizations/2014/antibiotics-currently-in-clinical-development.


5 Ibid.


7 U.S. Centers for Disease Control and Prevention, Antibiotic Resistance Threats.

For further information, please visit:
pewtrusts.org/antibiotic-pipeline